

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

NOV 17 1998

Ex parte WOLFGANG R. STREBER,
KENNETH N. TIMMIS and MEINHART H. ZENK

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 94-0224
Application 07/322,604¹

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and
MCKELVEY, Senior Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 17, 18, 23, 32, 33, 35, 42, 43, and 45-53. Claims 10-16, 19-22, 24-31, 34, 36-41, and 44 are pending but have been withdrawn from consideration by the examiner.

¹ Application for patent filed March 10, 1989.

Appeal No. 94-0224
Application 07/322,604

Claims 45 and 46² are illustrative of the subject matter on appeal and read as follows:

45. A recombinant gene, comprising

a DNA sequence encoding a polypeptide having the biological activity of 2,4-D monooxygenase which is capable of being expressed in a plant, operably linked to

a heterologous promoter capable of promoting the expression in a plant of a structural gene operably linked thereto.

46. A recombinant gene of claim 45, wherein the DNA sequence is

the structural gene sequence of Figure 10, except that the initiation codon is ATG,

a DNA sequence differing therefrom by codon degeneracy, or

a DNA sequence hybridizable therewith or its complement, wherein the sequence or its complement codes for a polypeptide having said biological activity.

The references relied upon by the examiner are³:

Béguin, Pierre, et al. (Béguin), "Sequence of a Cellulase Gene of the Thermophilic Bacterium Clostridium thermocellum", 162 Journal of Bacteriology, No. 1, 102-105 (Apr. 1985).

² Claim 46 was amended after the final rejection. The amendment was approved for entry by the examiner in the Advisory Action of May 22, 1992. However, the amendment has not been entered in the record. We reproduce the claim as amended. Upon return of the application, the examiner should see to it that the amendment is entered.

³ The examiner lists a U.S. patent as being relied upon in a rejection of the claims under appeal at page 3 of the examiner's answer. However, that patent has not been applied in any of the pending rejections.

Appeal No. 94-0224
Application 07/322,604

Amy, Penny et al. (Amy), "Characterization of Aquatic Bacteria and Cloning of Genes Specifying Partial Degradation of 2,4-Dichlorophenoxyacetic Acid", 49 Applied and Environmental Microbiology, No. 5, 1237-1245 (May 1985).

Comai, L, et al. (Comai), "Expression in plants of a mutant aroA gene from Salmonella typhimurium confers tolerance to glyphosate", 317 Nature, 741-744 (Oct. 1985).

Claims 23, 32, 33, 35, 42, 43, 45, 48 and 51-53 stand rejected under 35 U.S.C. § 112, first paragraph, as being nonenabled. Claim 46 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 17, 18, 23, 32, 33, 35, 42, 43 and 45-53 stand rejected under 35 U.S.C. § 103 as unpatentable over Amy and Béguin in view of Comai.

We reverse. In addition, we remand the application for the examiner to consider additional issues.

DISCUSSION

1. Enablement

The only reason given by the examiner in setting forth this rejection in the paragraph bridging pages 3-4 of the examiner's answer is that "the specification is not enabling for the isolation of production of any 2,4-D monooxygenase gene from any source." By now it is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi,

The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

2. Definiteness

The examiner considers claim 46 to be indefinite in regard to its requirement directed to “a DNA sequence hybridizable” with the structural gene sequence of Figure 10 of this application. The examiner indicates at page 4 of the examiner’s answer that this claim requirement is indefinite because the claim “places no functional or size limits on said DNA.” This is incorrect.

The last clause of claim 46 clearly requires that the “DNA sequence hybridizable” is to have “said biological activity.” The specified biological activity is that which is set forth in claim 45, i.e., “the biological activity of 2,4-D monooxygenase.” Thus, contrary to the examiner’s assertion, claim 46 does require the “DNA sequence hybridizable” to have a specified function.

The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

3. Prior Art

Claim 45 is directed to a recombinant gene which comprises two DNA sequences. The first DNA sequence encodes a polypeptide having the biological activity of 2,4-D monooxygenase which is capable of being expressed in a plant. The second DNA sequence is a heterologous promoter capable of promoting the expression in a plant of a structural gene operably linked thereto. According to claim 45, the two DNA sequences are to be “operably linked.”

Appellants do not dispute the examiner's finding that Amy describes a DNA sequence which encodes a polypeptide having the biological activity of 2,4-D monooxygenase. Nor do appellants dispute the examiner's finding that Comai describes a promoter capable of promoting the expression in a plant of a structural gene. Nor does it appear to be appellants' position that one of ordinary skill in the art having possession of these two DNA sequences would not be able to physically link the two sequences together. Rather, appellants' position on appeal appears to be that one of ordinary skill in the art would not have reasonably expected that such a DNA construct would be capable of being expressed in plant cells. See, e.g., page 5 of the Appeal Brief. In support of their position, appellants rely upon a declaration filed under 37 CFR § 1.132 by co-appellant Dr. Wolfgang R. Streber.

In his declaration, Dr. Streber takes the position that Comai would not have formed a basis for one to reasonably expect that the recombinant gene of claim 45 could be expressed in plants. Dr. Streber bases his opinion upon the fact that Comai only inserted an additional copy of a gene which was already present in a plant where the present invention adds a completely exogenous bacterial gene to a plant. Dr. Streber concludes (declaration, page 2):

There was no way to predict from [Comai], either alone or in combination with the other cited reference, whether:

- a) the bacterial 2,4-D monooxygenase could be expressed inside eukaryotic cells, e.g., plant cells, and

- b) even if it were, if the biological activity of the 2,4-D monooxygenase would be retained, and,
- c) even if it were, if it would be retained at a level compatible with both
 - I) the biological activity of herbicide-resistance and
 - ii) the viability of the plant.

Dr. Streber concludes at page 3 of his declaration:

Therefore, in view of the differences in the enzymes, in particular the endogenous versus exogenous nature of the enzymes, the very different chemistry of the herbicides, the metabolic pathways affected, the toxicity of reaction products, etc., between the reference and the present invention, a skilled worker would not be able to predict anything from the cited references, particularly in view of Comai, with respect to the present invention.

In response, the examiner states at page 9 of the Answer:

In the instant case, an artisan would have known that a structural gene from a gram negative bacterial source had been successfully expressed in a plant system prior to the time of the instant invention and would have reasonably expected that any other bacterial genes could also be expressed in a plant, absent unexpected results.

In essence, the examiner has taken the single success described by Comai and extrapolated that success into a generic teaching. Having done that, the examiner then takes the generic teaching and turns that into a per se rule, i.e., it would have been obvious at the time of the present invention to transform any plant with any bacterial gene and expect that that gene would be expressed in the plant, yet not harm the plant. The examiner's position falls from its own weight.

The rejection under 35 U.S.C. § 103 is reversed.

REMAND

Claim 45 is directed to a genus of recombinant genes, the DNA sequences of which are described functionally. As set forth in University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) claiming a DNA sequence by function "without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition."

Upon return of the application, the examiner should consider the claims on appeal in light of this decision and take appropriate action.

REVERSED; REMANDED

Sherman D. Winters
SHERMAN D. WINTERS)
Administrative Patent Judge)
William F. Smith)
WILLIAM F. SMITH) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
Fred E. McKelvey) INTERFERENCES
FRED E. MCKELVEY, Senior)
Administrative Patent Judge)

Appeal No. 94-0224
Application 07/322,604

William F. Lawrence, Esq.
Frommer, Lawrence & Haug, LLP
745 Fifth Avenue
New York, NY 10151